UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

CRYSTAL WINGFIELD, INDIVIDUALLY, AS NEXT OF KIN OF BETTY YOUNG AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF BETTY YOUNG, DECEASED, Plaintiff, v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Defendant.	**COMPLAINT AND JURY DEMAND** Civil Action No:

COMPLAINT

Plaintiff Crystal Wingfield, Individually, As Next of Kin of Betty Young, and as Personal Representative of the Estate of Betty Young, (hereinafter "Plaintiff"), by and through Plaintiff's attorneys, brings this action for Wrongful Death and Estate Claims against Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (hereinafter "Defendant"). Plaintiff alleges as follows:

PARTIES

1. At all times relevant hereto, Plaintiff was a resident and citizen of Acworth, Cherokee County, Georgia. Prior to her death, Betty Young resided in Canton, Cherokee County, Georgia.

2. Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") is a Delaware Corporation which has its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Boehringer may be served at CT Corporation System, 289 S Culver St, Lawrenceville, GA, 30046. Boehringer has conducted business and derived substantial revenue from within the State of Georgia.

JURISDICTION AND VENUE

3. This court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in the controversy as to Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendant is incorporated and has its principal places of business in states other than the state in which the named Plaintiff resides.

4. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. §1367.

5. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2), a judicial district in which a substantial part of the events or omissions giving rise to

the claim occurred in that Betty Young ingested Pradaxa and suffered injuries and death as a result in this District, and more specifically in the Atlanta Division.

FACTUAL BACKGROUND
Background of the Case

6. At all relevant times, Defendant, directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold Pradaxa® (dabigatran etexilate mesylate).

7. Pradaxa® is a direct thrombin inhibitor that is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Patients with atrial fibrillation have an increased risk of stroke.

8. Pradaxa® was approved by the Food and Drug Administration ("FDA") on October 19, 2010. The FDA approved two dosages: 75 mg and 150 mg, to be taken twice daily. Pradaxa® was the first anticoagulation medication approved in the U.S. in more than 50 years for patients with non-valvular atrial fibrillation.

9. Prior to the FDA's approval of Pradaxa®, warfarin was the only oral anticoagulation available in the U.S. for reducing stroke and systemic embolism in patients with atrial fibrillation. Unlike patients who use Pradaxa®, users of warfarin must follow dietary restrictions and regularly monitor their blood levels

(INR) by undergoing blood tests and potentially adjusting the dose of their medication.

Defendants' over promotion of Pradaxa®

10. Defendant promoted Pradaxa® as a novel medicine for patients with non-valvular atrial fibrillation. Defendant's marketing campaign for Pradaxa® included promoting it as being more effective than warfarin in preventing stroke and systemic embolism, providing a convenient alternative to warfarin therapy because it does not require blood monitoring or dose adjustments, and does not require any dietary restrictions.

11. Defendant spent significant money in promoting Pradaxa®, which included $67,000,000.00 spent during 2010 (although Pradaxa® was not approved for sale until October 19, 2010.)[1]

12. During 2011, Defendant reportedly undertook 1.5 million Pradaxa® "detailing sessions" (marketing/sales visits by Defendants' sales force) with U.S. primary care physicians, internists, group practitioners, cardiologists, and practice nurses, spending approximately $464,000,000.00 during this 12 month period to promote Pradaxa® in the United States.[2]

---

[1] Deborah Weinstein, *Study: Sales Support is Dwindling, Not Dead,* March 14, 2012, Medical Marketing and Media.
[2] *Id.*

13. As part of the marketing of Pradaxa®, Defendant widely disseminated direct-to-consumer advertising campaigns that were designed to influence patients, including Plaintiff's Decedent, Betty Young, to make inquiries to their prescribing physician about Pradaxa® and/or request prescriptions for Pradaxa®.

14. In the course of these direct to consumer advertisements, Defendant overstated the efficacy of Pradaxa® with respect to preventing stroke and systemic embolism while understating the risk of serious bleeding complications.

15. Prior to Betty Young's prescription of Pradaxa®, Betty Young became aware of the promotional materials described herein.

16. Prior to Betty Young's prescription of Pradaxa®, her prescribing physician received promotional materials and information from sales representatives of Defendant that Pradaxa® was more effective than warfarin in reducing strokes in patients with non-valvular atrial fibrillation and was more convenient.

17. From October 2010 until the end of March 2011, approximately 272,119 prescriptions for Pradaxa® were written in the United States. During that same period, there were 932 Pradaxa®-associated "Serious Adverse Event" ("SAE") Medwatch reports filed with the U.S. Food and Drug Administration, including at least 120 deaths and over 500 reports of severe, life-threatening bleeding.

18. From April 1 until the end of June 2011, there were an additional 856 Pradaxa®-associated "SAE" Medwatch reports filed with the U.S. Food and Drug Administration including at least 117 deaths and over 510 reports of severe, life-threatening bleeding.

19. During the Defendant's 2011 fiscal year, worldwide Pradaxa® sales eclipsed the $1 billion threshold, achieving what is commonly known in the pharmaceutical industry as "blockbuster" sales status.[3]

20. Defendant's original labeling and prescribing information for Pradaxa®:

a. failed to investigate, research, study and consider, fully and adequately, patient weight as a variable factor in establishing recommended dosages of Pradaxa®;

b. failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa®;

c. failed to provide adequate warnings about the true safety risks associated with the use of Pradaxa®;

d. failed to warn that it is difficult to assess the degree and/or extent of anticoagulation in patients taking Pradaxa®;

[3] Heide Oberhauser-Aslan and Tapan Sharma, *Boehringer Sees Sales Rising Further as 2011 Profits Surge* April 24, 2012 WSJ.com.

e. failed to provide instructions for physicians to assess the degree and/or extent of anticoagulation in patients taking Pradaxa®;

f. failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Pradaxa®;

g. failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Pradaxa® and to continue testing and monitoring of renal functioning periodically while the patient is on Pradaxa®;

h. failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Pradaxa® users; and

i. failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Pradaxa®, especially, in those patients with a prior history of gastrointestinal issues and/or upset.

21. In March 2011, Defendant modified the U.S. labeling and prescribing information for Pradaxa®, which included additional information regarding the use of Pradaxa® in patients taking certain medications. Despite being aware of: (I) serious, and sometimes fatal, irreversible bleeding events associated with the use of

Pradaxa®; (II) almost 1,800 SAE Medwatch reports filed with the U.S. Food and Drug Administration, including at least 237 deaths and over 1,000 reports of severe, life-threatening bleeding, Defendant nonetheless failed to provide adequate disclosures or warnings in the label as detailed in Paragraph 20 (a – i) above.

22. On July 1, 2011, Pradaxa® was approved for sale in New Zealand with lower dosing (lowered from 150mg to 110mg twice a day) required for patients over 80 years of age and recommended for patients with moderate renal impairment.

23. On July 25, 2011, the Archives of Internal Medicine published *The Use of Dabigatran* [Pradaxa®] *in Elderly Patients*. [Vol 171, No. 14] which concluded that "The risk of major over dosage of…[Pradaxa®] in this [elderly] population is, however, much increased owing to frequent renal function impairment, low body weight, drug interactions that cannot be detected with a routine coagulation test and no antagonist available."

24. On January 21, 2011, Pradaxa® (under the brand name Prazaza®), in 75mg and 110mg doses only, is approved for sale in Japan to treat non-valvular atrial fibrillation.

25. On August 11, 2011, Japan's pharmaceutical regulatory authority announced that it was requiring a "**BOXED WARNING**" be added to Pradaxa®

(marketed as Prazaza® in Japan) to call attention to reports of severe hemorrhages in patients treated with Pradaxa® (Prazaza®).

26. On September 1, 2011, the New Zealand pharmaceutical regulatory authority issued a "Prescriber Update" entitled "Dabigatran – Is there a Bleeding Risk" in which physicians were alerted that Pradaxa® had a higher incidence of gastrointestinal bleeds than warfarin. A follow-up report issued in December 2011, indicated that among 10,000 New Zealanders who had taken Pradaxa®, there were 78 reports of serious bleeding events associated with Pradaxa® including 60 reports of gastrointestinal and rectal bleeding. Among the 78 serious events were 10 patient deaths and 55 hospitalizations. Three months later in March, 2012 the New England Journal of Medicine published two letters from physicians in New Zealand addressing bleeding events associated with Pradaxa®. In one letter, physicians wrote, "We are concerned that the potential risks of this medication are not generally appreciated."

27. In November 2011, Defendant modified the U.S. labeling and prescribing information for Pradaxa® adding additional information regarding the use of Pradaxa® in patients with kidney disease despite being aware of: (I) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (II) the July 25, 2011 article in the *Archives of Internal Medicine*; (III) the addition of a "**BOXED WARNING**" to Pradaxa® in Japan; and, (IV) the

questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®, Defendant nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraph 20 (a – i) above.

28. On December 7, 2011, the U.S. Food and Drug Administration issued a Drug Safety Communication announcing that it was undertaking a "Drug Safety Review" of Post-Marketing Reports of Serious Bleeding Events with the anticoagulant Pradaxa. The purpose of the FDA's review is to determine if serious bleeding events associated with the use of Pradaxa® are more common than expected based on the Defendant's data submitted to the FDA.

29. As of December 31, 2011, the U.S. Food and Drug Administration received over 500 reports of deaths of people in the U.S. linked to Pradaxa® which, at that point, had been available in the U.S. for approximately 14 months. In addition, there were over 900 reports of gastrointestinal hemorrhages, over 300 reports of rectal hemorrhages, and over 200 reports of cerebrovascular accidents suffered by U.S. citizens associated with Pradaxa®.

30. In January 2012, the Defendant modified the U.S. labeling and prescribing information for Pradaxa®. Despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) the July 25, 2011 article in the *Archives of Internal Medicine*; (iii) the addition of a "**BOXED WARNING**" to Pradaxa® in Japan; (iv) the questions being raised

by physicians in New Zealand about serious bleeding events associated with Pradaxa®; and (v) the Drug Safety Communication published by the FDA in December, 2011, Defendant nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraph 20 (a – i) above.

31. In March 2012, in response to a directive from Health Canada, the governmental agency responsible for regulating pharmaceuticals in Canada, Defendant's Canadian affiliate issued a "Dear Healthcare Provider" letter in which it advised Canadian healthcare providers of certain risks associated with the use of Pradaxa® (marketed as Pradax® in Canada) in elderly patients and patients with impaired kidney function and prosthetic heart valves. No such similar communication was sent to healthcare providers in the United States.

32. In April 2012, the Defendant modified the U.S. labeling and prescribing information for Pradaxa®. Despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) the July 25, 2011 article in the Archives of Internal Medicine; (iii) the addition of a "**BOXED WARNING**" to Pradaxa® in Japan; (iv) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®; (v) the Drug Safety Communication published by the FDA in December, 2011; and (vi) the "Dear Healthcare Provider" letter Defendants were

required to provide in Canada, Defendant nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraph 20 (a – i) above.

Decedent Betty Young's use of Pradaxa® and resulting injuries

33. As a result of Defendant's claims regarding the effectiveness, safety, and benefits of Pradaxa®, Betty Young and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence that Betty Young would be exposed to the risk of excessive and/or uncontrollable bleeding and the other risks and injuries described herein.

34. Therefore, Betty Young was prescribed Pradaxa® for treatment of non-valvular atrial fibrillation. Thereafter, Betty Young experienced a major gastrointestinal bleeding event on or about November 16, 2016, causing her to be hospitalized until November 23, 2018 at Northside Hospital in Canton, Georgia. As a result of her major gastrointestinal bleed while on Pradaxa, Betty Young was unable to take any anticoagulation medication thereafter. As a result of not being anticoagulated, Betty Young suffered an acute massive pulmonary embolism on or about December 10, 2016, and died as a result on December 14, 2016. Betty Young was eighty-two (82) years old at the time of her death, with a future life expectancy of 8.48 years. *See* O.C.G.A. §§ 24-4-44 & 24-4-45.

35. Prior to Betty Young's use of Pradaxa®, Defendant knew or should have known that the labeling of the drug did not adequately warn of the risks associated with using the drug as described above.

36. Prior to Betty Young's use of Pradaxa®, Defendant knew or should have known of the defective nature of Pradaxa® and persons who were prescribed and ingested Pradaxa®, including Betty Young, were at increased risk for developing life-threatening bleeds. Defendant, through its affirmative misrepresentations and omissions, concealed from Betty Young and her physicians the true and significant risks associated with Pradaxa® use.

37. Betty Young was unaware of the increased risk for developing life-threatening injuries on Pradaxa as compared to warfarin. Had Betty Young and/or her healthcare provider known of the risks and dangers associated with Pradaxa®, and had Defendant provided adequate instructions regarding appropriate dosing and monitoring of patients on Pradaxa, Betty Young would not have used Pradaxa® and/or would have been prescribed a lower dose of Pradaxa®.

38. As a direct and proximate result of Betty Young using Pradaxa®, Plaintiff has suffered personal injuries, economic and non-economic damages, including pain and suffering and wrongful death as previously described herein.

CAUSES OF ACTION

COUNT I
STRICT LIABILITY-FAILURE TO WARN

39. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

40. At all times relevant to this suit, Defendant engaged in the business of designing, manufacturing, testing, marketing, labeling and placing into the stream of commerce Pradaxa® for sale to, and use by, members of the public.

41. At all times relevant to this suit, the dangerous propensities of Pradaxa® were known to Defendant, or were reasonably and scientifically knowable to Defendant, through appropriate research and testing by known methods, at the time it distributed, supplied, or sold the product, and not known to ordinary physicians who would be expected to prescribe the drug for their patients.

42. The Pradaxa® manufactured by Defendant reached Betty Young without substantial change and was ingested as directed.

43. Defendant marketed Pradaxa® in multiple ways, including but not limited to direct-to-consumer advertisements, which were misleading in that Defendant overstated the safety and efficacy of Pradaxa® and understated its risks.

44. The Pradaxa® was defective and unreasonably dangerous in that the labeling was insufficient to adequately warn physicians and users of the increased risk of excessive and/or uncontrollable bleeding.

45. As a direct and proximate result of the actions and inactions of the Defendant as set forth above, Betty Young was exposed to Pradaxa® and Plaintiff suffered personal injuries, economic and non-economic damages including pain and suffering, and wrongful death.

46. Defendant's actions and omissions as identified in this Complaint show that Defendant acted maliciously and/or intentionally disregarded the Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT II
STRICT PRODUCTS LIABILITY - DESIGN DEFECT

47. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

48. Defendant is the manufacturer, designer, distributer, seller and supplier of Pradaxa®, who sold Pradaxa® in the course of business.

49. The Pradaxa® manufactured, designed, sold, marketed, distributed, supplied and/or placed in the stream of commerce by Defendant was expected to and did reach the consumer without any alterations or changes.

50. The Pradaxa® administered to Betty Young was defective in design or formulation in at least the following respects:

a. When it left the hands of the Defendant, this drug was unreasonably dangerous to an extent beyond that which could reasonably be contemplated by Betty Young or her physicians;

b. Any benefit of this drug was outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendant intended;

c. The dosages and/or formulation of Pradaxa® sold by the Defendant were unreasonably dangerous;

d. There are patients for whom the benefits of Pradaxa® do not outweigh the risks;

e. The product was not made in accordance with the Defendant's specifications or performance standards;

f. There are patients for whom Pradaxa® is not a safer or more efficacious drug than other drug products in its class; and/or

g. There were safer alternatives that did not carry the same risks and dangers that Defendant's Pradaxa® had.

51. The Pradaxa® administered to Betty Young was defective at the time it was distributed by the Defendant or left its control.

52. The foreseeable risks associated with the design or formulation of the Pradaxa® include, but are not limited to, the fact that the design or formulation of Pradaxa® is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or did not have the claimed benefits.

53. The defective and unreasonably dangerous design and marketing of Pradaxa® was a direct, proximate and producing cause of Betty Young's pre-death injuries and death. Under strict products liability theories set forth in Restatement (Second) of Torts, Defendants is liable to Plaintiff for all damages claimed in this case.

54. As a direct, legal, proximate, and producing result of the defective and unreasonably dangerous condition of Pradaxa®, Plaintiff suffered personal injuries, economic and non-economic damages, including pain and suffering, and wrongful death.

55. Defendant's actions and omissions as identified in this Complaint show that Defendant acted maliciously and/or intentionally disregarded the Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT III
NEGLIGENCE

56. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

57. Defendant owed a duty to the general public and specifically to Betty Young to exercise reasonable care in the design, study, development, manufacture, promotion, sale, labeling, marketing and distribution of Pradaxa® at issue in this lawsuit.

58. Defendant breached its duty and failed to exercise reasonable care in the developing, testing, designing and manufacturing of Pradaxa® because it was capable of causing serious personal injuries and death, such as suffered by Betty Young, during foreseeable use.

59. Defendant breached its duty and also failed to exercise reasonable care in the marketing of Pradaxa® because they failed to warn, that as designed, Pradaxa® was capable of causing serious personal injuries and death, such as suffered by Betty Young, during foreseeable use.

60. Defendant breached its duty and also failed to exercise ordinary care in the labeling of Pradaxa® and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Pradaxa®. Moreover, Defendant over-promoted the benefits of Pradaxa® for anticoagulation therapy in patients suffering from atrial fibrillation and understated the risk of excessive and/or uncontrollable bleeding.

61. Defendant breached its duty and was negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiff:

a. In disseminating information to Betty Young and her physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Betty Young;

b. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Pradaxa®;

c. Failing to design and/or manufacture a product that could be used safely due to the lack of instruction as to how to ensure that the patient did not have too much Pradaxa in her blood; and

d. In designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendant knew or should have known could cause injury to Plaintiff.

62. Despite the fact that Defendant knew or should have known that Pradaxa® posed a serious risk of bodily harm to consumers and/or did not provide any additional benefits, Defendant continued to manufacture and market Pradaxa® for use by consumers.

63. Defendant knew or should have known that consumers, including Betty Young, would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above.

64. Defendant's failure to exercise reasonable care in the design, dosing information, marketing, warnings, labeling, and/or manufacturing of Pradaxa® was

a proximate cause of the Plaintiff's personal injuries, economic and non-economic damages, including pain and suffering, and wrongful death.

65. Defendant's conduct as described above, including but not limited to its failure to adequately test Pradaxa®, to provide adequate warnings, and its continued manufacture, sale and marketing of the product when it knew or should have known of the serious health risks it created, evidences actions and/or intentional disregard of the rights of the Plaintiff so as to warrant the imposition of punitive damages.

COUNT IV
NEGLIGENT MISREPRESENTATION AND/OR FRAUD

66. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

67. Defendant represented that Pradaxa® was just as safe or safer and as effective or more effective than other anticoagulation alternatives and had additional benefits compared to other anticoagulation medications available on the market.

68. Defendant made these misrepresentations and actively concealed adverse information at a time when the Defendant knew, or should have known, that Pradaxa® had defects, dangers, and characteristics that were other than what Defendant had represented to Betty Young, her physicians, and the health care

industry generally. Specifically, Defendant misrepresented to and/or actively concealed from Betty Young and the consuming public, among other things, that:

a. Pradaxa® had statistically significant increases in major bleeds and other side effects which could result in serious, permanent injury or death;

b. Pradaxa® had not been fully or adequately tested;

c. Pradaxa® blood concentrations above a certain level subject patients to an increased, and unnecessary, risk of bleed;

d. The difficulty in assessing the degree and/or extent of anticoagulation in patients taking Pradaxa® utilizing the information contained in the Pradaxa label; and

e. Pradaxa® was not as safe as other blood thinners.

69. Defendant negligently and/or intentionally misrepresented or omitted this information in the product labeling, promotions and advertisements, and instead labeled promoted and advertised the product as safer and more effective than other types of anticoagulation alternatives and understated the risk of excessive and/or uncontrollable bleeding associated with Pradaxa®.

70. The aforementioned misrepresentations were untrue and misleading.

71. Defendant knew or should have known that these representations were false and made the representations with the intent that Betty Young and/or her prescribing physicians would rely on them, leading to the use of Pradaxa®.

72. At the time of Defendant's fraudulent misrepresentations, Betty Young and/or her prescribing physicians were unaware of the falsity of the statements being made and believed them to be true. Betty Young and/or her prescribing physicians justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information, which Defendant did suppress, conceal or failed to disclose, to Plaintiff's detriment.

73. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendant, Plaintiff suffered personal injuries, economic and noneconomic damages, including pain and suffering, and wrongful death.

74. Defendant's actions and omissions as identified in this Complaint demonstrate malicious actions and/or intentional disregard of the Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT V
FRAUDULENT CONCEALMENT

75. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

76. At all times during the course of dealings between Defendant and Betty Young, and/or her healthcare providers, and/or the FDA, Defendant misrepresented the safety of Pradaxa® for its intended use.

77. Defendant knew or was reckless in not knowing that its representations were false.

78. In representations to Betty Young, and/or her healthcare providers, and/or the FDA, Defendant fraudulently concealed and intentionally omitted the following material information:

a. that Pradaxa® was not as safe or effective as other forms of anticoagulation medication for atrial fibrillation patients;

b. that Defendant failed to investigate, research, study and consider, fully and adequately, patient weight as a variable factor in establishing recommended dosages of Pradaxa®;

c. that Defendant failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa®;

d. that Defendant failed to provide adequate instructions as to how and when to measure the anticoagulation effects of Pradaxa®;

e. that Defendant failed to include an adequate warning about serious bleeding events associated with Pradaxa®;

f. that Defendant failed to warn it is difficult to assess the degree and/or extent of anticoagulation in patients taking Pradaxa® utilizing the information contained in the Pradaxa label;

g. that Defendant failed to adequately instruct physicians on how to intervene and/or stabilize a patient who suffers a bleed while taking Pradaxa®;

h. that it is critical to fully assess renal functioning prior to starting a patient on Pradaxa® and to continue testing and monitoring of renal functioning periodically while the patient is on Pradaxa®;

i. that there is an increased risk of bleeding events associated with aging patient populations of Pradaxa® users;

j. that there is an increased risk of gastrointestinal bleeds in those taking Pradaxa®, especially, in those patients with a prior history of gastrointestinal issues and/or upset;

k. that Pradaxa® was defective, and that it caused dangerous side effects, including but not limited to higher incidence of excessive and/or uncontrollable bleeding;

l. that Pradaxa® was manufactured negligently;

m. that Pradaxa® was manufactured defectively;

n. that Pradaxa® was manufactured improperly;

o. that Pradaxa® was designed negligently;

p. that Pradaxa® was designed defectively; and

q. that Pradaxa® was designed improperly.

79. Defendant was under a duty to disclose to Betty Young, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Pradaxa®, including but not limited to the heightened risks of excessive and/or uncontrollable bleeding.

80. Defendant had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Pradaxa®, including Betty Young, in particular.

81. Defendant's concealment and omissions of material facts concerning, *inter alia*, the safety of Pradaxa® was made purposefully, willfully, wantonly, and/or recklessly, to mislead Betty Young, and her physicians, hospitals and healthcare providers into reliance, continued use of Pradaxa®, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Pradaxa® and/or use the product.

82. Defendant knew that Betty Young and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind

Defendant's concealment and omissions, and that these included material omissions of facts surrounding Pradaxa®, as set forth herein.

83. Betty Young and her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendant.

84. As a result of the foregoing acts and omissions Betty Young was caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, *inter alia*, excessive and/or uncontrollable bleeding, as well as other severe and personal injuries, physical pain and mental anguish, including diminished enjoyment of life, and death.

85. As a result of the foregoing acts and omissions, Betty Young required health care and services and incurred medical, health, incidental and related expenses. Plaintiff also suffered the wrongful death of Betty Young.

86. By reason of the foregoing, Plaintiff has been damaged.

COUNT VI
PUNITIVE DAMAGES

87. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

88. At all material times, the Defendant knew or should have known that Pradaxa® was inherently dangerous.

89. Despite such knowledge, the Defendant continued to aggressively market Pradaxa® to consumers, including Betty Young, without disclosing its dangerous side effects when there existed safer alternative products, such as Warfarin/Coumadin.

90. Despite Defendant's knowledge of Pradaxa®'s defective and unreasonably dangerous nature, Defendant continued to test, design, develop, manufacture, label, package, promote, market, sell and distribute it so as to maximize sales and profits at the expense of the health and safety of the public, including Betty Young, in conscious disregard of the foreseeable harm caused by Pradaxa®.

91. Defendant's conduct was intentional and/or wanton.

92. Defendant's conduct as described above, including, but not limited to, its failure to adequately test the product, to provide adequate warnings, and its continued manufacture, sale, and marketing or the product when it knew or should have known of the serious health risks created, was intentional, willful wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences in that Defendant acted only out of self-interest and personal gain. Such conduct evidences a specific intent to cause harm to Plaintiff as provided under O.C.G.A. § 51-12-5.1. Accordingly, punitive damages should be imposed against Defendant

pursuant O.C.G.A. § 51-12-5.1 and others applicable laws, to punish and deter Defendant from repeating or continuing such unlawful conduct.

COUNT VII
PRE-DEATH INJURY AND PAIN AND SUFFERING

93. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

94. As a direct and proximate result of the acts and omissions of Defendant, Betty Young was injured and suffered damages prior to her death, for which Plaintiff may recover including, but not limited to: pre-death physical injury; pre-death physical pain and suffering; pre-death mental pain and suffering; pre-death impairment, disability and disfigurement; loss of capacity to enjoy life; loss of capacity to work or earn a living; loss of time in life that could have been spent doing things other than going to doctors; physically suffering, and undergoing medical procedures; pre-death expenses of hospitalization, medical care, nursing care, other treatment and medical monitoring; pre-death fear and mental anguish associated with Betty Young's impending death; as well as all other special and general damages permitted under law.

COUNT VIII
WRONGFUL DEATH

95. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

96. As a result of the individual, combined and concurring acts and omissions of Defendant as set forth herein above caused or contributed to cause injuries to Betty Young for which Plaintiff may recover. Such damages include damages which may be recovered for:

a) The homicide and wrongful death of Betty Young, deceased, entitling Plaintiff to recover the full value of Betty Young's life, as well as all other damages permitted under law;

b) Expenses associated with the last illness, death and burial of Betty Young;

c) Pre-death physical injury, pain and suffering, disability, impairment, lost capacity to enjoy life, mental anguish, and lost earnings of Betty Young in an amount to be proven at trial which may be recovered by Plaintiff;

d) Pre-death medical expenses of Betty Young in an amount to be proven at trial; and

e) Pre-death fear and mental anguish of Betty Young concerning existing and future medical problems in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

(a) That process issue according to law;

(b) That Defendant be served with a copy of Plaintiff's Complaint For Damages and show cause why the prayers for relief requested by Plaintiff herein should not be granted;

(c) That Plaintiff be granted a **trial by jury** in this matter;

(d) That the Court enter a judgment against Defendant for all general and compensatory damages allowable to Plaintiff;

(e) That the Court enter a judgment against Defendant for all special damages allowable to Plaintiff;

(f) That the Court enter a judgment against Defendant serving to award Plaintiff punitive damages under the provisions of O.C.G.A. § 51-12-5.1;

(g) That Plaintiff recover all possible damages for the wrongful death of Betty Young;

(h) That the Court enter a judgment against Defendant for all other relief sought by Plaintiff under this Complaint;

(i) That the costs of this action be cast upon Defendant; and

(j) That the Court grant Plaintiff such further relief which the Court deems just and appropriate.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: November 16, 2018

RESPECTFULLY SUBMITTED,

/s/: C. Andrew Childers
CHILDERS, SCHLUETER & SMITH, LLC
C. Andrew Childers, Esq.
Georgia Bar No. 124398
1932 North Druid Hills Road, Suite 100
Atlanta, Georgia 30319
(404) 419-9500 – Telephone
(404) 419-9501 – Facsimile
achilders@cssfirm.com

ATTORNEY FOR PLAINTIFF